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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Robert W. Kreis

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07/01/2009

CONVATEC INC.

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/719,183	Applicant(s) KREIS ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action, request for extension of time (2 months-granted) and Applicant's Arguments/Remarks, all filed 03/31/09 is acknowledged.

Claims 1 and 9-16 are pending in this action. No amendments to the claims have been made. Claims 2-8 have previously been cancelled. Claims 1 and 9-16 remain rejected.

* * * * *

Claim Rejections - 35 USC § 112

New Matter

Claims 1 and 9-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's recitation of vertical wicking "*perpendicular to the plane of the dressing*" in instant claims 1, 13 & 15 presents new matter. A review of the instant specification indicates that there is lack of support for this limitation in the present specification. Applicant has directed the Examiner to pages 3 and 8 of the specification, however, the passages referred to by Applicant only discuss 'vertical wicking of wound exudate away from the wound'. There is no reference point addressing the particular direction (perpendicular to the plane of the dressing) based on the vertical wicking property. There is no definition provided that would support Applicant's limitation of "perpendicular to the plane of the dressing" as now claimed by Applicant.

* * * * *

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlisle (U.S. Pat. No. 3,824,996) in view of Dyer *et al.* (U.S. Pat. No. 5,899,893) and further in view of Bernardin *et al.* (U.S. Pat. No. 5,124,197).

Carlisle ('996) teaches highly absorbent pressure dressings for wounds substantially constructed from cellulosic, fibrous material formed in thin layers and adapted to be applied and affixed to curved surfaces of the human body (see claims and Abstract).

According to Carlisle, the dressings have a finely porous, highly dense fibrous construction which provides the dual advantages of dispersing absorbed exudates to a low interlayer adhesion level, and preventing healing tissues from becoming entangled with the dressing's fibrous material (col. 3, lines 53-67). Carlisle teaches the significance of speed of absorption, direction of absorption and the length of wicking (col. 4, lines 1-14). The chart at column 4 demonstrates that the dressing of Carlisle absorbs fluid steadily and continuously (i.e., wicking) (see col. 4, lines 15-55).

Carlisle teaches that the dressing layer materials can absorb distilled water *vertically* against gravity continuously for more than 5 hours (see claim 4). Carlisle also teaches that the dressing, when affixed and held in place with retaining material, adapts to exert relatively even pressure on the wound surface which tends to improve the quality of the repair tissue formed during healing (claim 17).

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The wound dressings can be applied to wounds, such as burns (col. 2, lines 63-67).

Suitable dressing materials taught includes hard and soft wood pulp (col. 5, lines 19-22) and fibrous dense cellulose materials (see claims 1, 5, 6, 18).

With regards to the claim limitation ‘for a period of time until after epithelial outgrowth and vertical wicking occur’ recited in instant claim 1, the Examiner notes that this limitation does not impart patentable weight to the claims. The limitation is relative in terms of the time required in which epithelial outgrowth and/or vertical wicking occurs since the limitation fails to set forth any specific time or duration parameters that is required for epithelial outgrowth and vertical wicking to occur. With regards to the amount of water (25 g/g) absorbed claimed in claims 12-15, Carlisle does not teach absorbing at least 25 g/g of deionized water. However, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts through routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. The particular method of treating an acute wound using a wound dressing and applying the wound dressing to the wound would be obvious in view of the disclosure of Carlisle. Carlisle clearly teaches highly absorbent pressure dressings for wounds, such as burns, constructed from cellulosic, fibrous material, whereby the dressings are applied and affixed to curved surfaces of the human body.

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In any event, **Dyer *et al.*** ('893) are relied upon for their teaching of absorbent articles, such as wound dressings, having a vertical wicking capability of at least about 30 g/g, more preferably at least about 40 g/g. Particularly preferred foam absorbents will wick at least about 45 g/g. The foam absorbents of the invention wick a high capacity of the test fluid to a particular height at equilibrium (see reference column 1, lines 11-19); (col. 2, line 45); (col. 7, lines 41-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the absorbent articles of Dyer *et al.* within the teachings of Carlisle. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Dyer *et al.* teach absorbent articles, particularly wound dressings and teach that their absorbent articles are able to wick at a high capacity at equilibrium, such as a vertical wicking capability of at least about 30 g/g, more preferably at least about 40 g/g and even at least about 45 g/g. The expected result would be a highly absorbent wound dressing that is beneficially used for the treatment of acute wounds.

Bernardin *et al.* ('197) are relied upon for the teaching of an absorbent web formed from inflated cellulose fibers whereby the web possesses improved vertical wicking properties (see col. 1, line 6 – col. 2, line 30); (col. 3, lines 16-28) and Abstract. The absorbent webs are suitable for use in forming absorbent products, such as dressings, incontinence products, feminine pads and the like (col. 6, lines 41-46). Suitable fibers used in the invention include natural fibers, such as wood fibers, cotton linters and cotton staple (col. 3, lines 46-58).

Bernardin *et al.* teach that as a general rule, the vertical wicking properties of a web will be considered improved when the web exhibits at least about a 20 percent increase in initial vertical wicking rate, vertical wicking capacity (at 15 or 30 minutes) or vertical fluid distribution

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(at a distance between nine and eighteen cm) when compared to a similar web (col. 4, lines 36-52).

Bernardin *et al.* teach that the improved vertical wicking properties of the webs allows fluid to be vertically wicked from one particular area of the web to another remote location on the web. The absorbent web is able to transport fluid from one location on the web to another location on the web, based on the improved vertical wicking properties (col. 7, lines 8-40).

It would have been obvious to incorporate the absorbent cellulose fibers that exhibit improved wicking properties within the highly absorbent pressure dressing of Carlisle. One of ordinary skill in the art would do so with a reasonable expectation of success because Bernardin *et al.* teach an absorbent web made of cellulosic fibers, for use in absorbent products such as dressings and teach that the vertical wicking properties allows the absorbent web to transport fluid from one location on the web to another location on the web, thus increasing the absorbent capacity of the absorbent web.

Regarding the limitation of “vertical wicking perpendicular to the plane of the dressing”, the Examiner notes that this limitation does not establish any patentable distinction that would accrue over the explicit reference teachings, which provides for the same components as claimed by Applicant. The prior art teaches absorbent webs formed from cellulose fibers, used in dressings, whereby the absorbent webs demonstrate improved vertical wicking properties (see Bernardin). No unexpected results have been observed which would occur as a result of the particular direction of wicking (perpendicular wicking of the instant invention versus lateral wicking of the art). The art is well aware of providing for absorbent products that demonstrate enhanced wicking capabilities. Given the teachings of Carlisle, Dyer *et al.* and Bernardin *et al.*

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delineated above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 03/31/09 have been fully considered but were not found to be persuasive.

▪ **35 U.S.C. §112, first paragraph:**

Applicant argued, "Contrary to the assertions in the rejection, the application actually discusses migration into the dressing, not merely away from the wound. As it is clear from the application, that migration is described with reference to the dressing in use. The combination of the term "into" with the expression "vertical wicking" defines that migration as being perpendicular to the plane of the dressing in use. This interpretation is also supported by original claims 7 and 8 which refer to vertical wicking into the dressing in use. It is alleged in the rejection that there is no reference point addressing the direction of the wicking. Applicants disagree with this as well. The reference point is the dressing in use. In that context, vertical is perpendicular to the plane of the dressing."

Applicant's arguments have been considered but were not found persuasive. The Examiner respectfully submits that ample support remains lacking for the limitation reciting, "perpendicular to the plane of the dressing". Applicant states that 'the combination of the term "into" with the expression "vertical wicking" defines that migration as being perpendicular to the plane of the dressing in use' and thus provides ample support. This was not deemed persuasive since the language recited in the specification is not sufficient to establish the generic concept argued by Applicant. The specific language of "perpendicular to the plane of the dressing" has not been provided for in the present specification and thus introduces new matter into the claims.

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The specification is sufficient to support the concept of vertical wicking, but not necessarily the language of "perpendicular to the plane of the dressing" as currently presented by Applicants. This rejection has been maintained.

- **35 U.S.C. §103(a) Rejection of claims 1 and 9-16 over Carlisle (U.S. Pat. No. 3,824,996) in view of Dyer et al. (U.S. Pat. No. 5,899,893) and Bernardin et al. (U.S. Pat. No. 5,124,197):**

Applicant argued, "Carlisle is concerned with pressure dressings. According to Carlisle, pressure dressings are fundamental in the preparation of wounds for skin grafting. Carlisle does not consider his dressing as a substitute for a biological dressing, but rather as a preparation for it. Carlisle, would not, therefore, motivate the person of ordinary skill to use a fibrous dressing as a substitute for a biological dressing. Further, dressings of Carlisle are dense, laminar dressings that wick laterally and bar the movement of exudates perpendicular to the plane of the dressing."

Applicant's arguments have been considered, but were not found persuasive. Carlisle teaches highly absorbent pressure dressings for wounds substantially constructed from cellulosic, fibrous material formed in thin layers and adapted to be applied and affixed to curved surfaces of the human body (see claims and Abstract). The fact that Applicants dressing can be used as a substitute for biological dressings does not provide for a patentable distinction over the wound dressings of the art. The Carlisle wound dressings are formed of the same materials as that of Applicant's dressing. Moreover, the highly absorbent pressure dressings of Carlisle are used to treat wounds and thus reads on the method of treatment of acute wounds claimed by Applicant.

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Thus, the argument that Applicants use their dressings as a 'substitute for a biological dressing' does not distinguish over the art, which also recognizes methods of treating wounds by application of dressings to the wounds in order to treat such wounds.

Applicant argued, "Carlisle does not teach that the dressing is left in place or vertical wicking and does not suggest that there would be any advantage in vertical wicking".

This argument was not persuasive. Carlisle recognizes that their wound dressing can be left on the skin for extended periods of time, such as two or more weeks, if desired (col. 3, lines 54-67). Applicants desire that their wound dressing is left in place, however this step does not impart any unexpected results or a patentable distinction over the Carlisle reference teachings. With regard to vertical wicking, Carlisle teaches that speed and direction of absorption and length of wicking is important for their dressing. While vertical wicking is not explicitly discussed, the reference of Bernardin et al. is relied upon for the teaching of absorbent webs formed from cellulose fibers, used in dressings, whereby the absorbent webs demonstrate improved vertical wicking properties. Thus, this limitation has been met.

Applicant argued, "The Action relies on Dyer, et al. to supply the deficiencies of Carlisle. However, there must be a suggestion in Carlisle to do so. Carlisle is concerned with pressure dressings that have limited compressibility. The dressing material of Dyer is foam, and it is well known that foams are highly compressible. Thus, a person having ordinary skill in the art would not substitute the foam of Dyer et al. for the lamellar dressing of Carlisle in order to improve the Carlisle dressing. Dyer does not demonstrate vertical wicking."

These arguments were not found persuasive. While Carlisle teach lateral wicking, rather than vertical wicking, Dyer et al. are relied upon to demonstrate that it is well known in the art to

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employ absorbent articles, such as wound dressings that have vertical wicking capability of at least about 30 g/g. Applicant's argument that "Carlisle teaches limited compressibility pressure dressings whereas Dyer is directed to a highly compressible foam" was not persuasive since both references are directed to highly absorbent articles used for wound dressing applications. Thus, this is a sufficient criterion to combine the references. Applicants stated that the "wicking in Dyer is the wicking of a vertically held strip of a test material against gravity." Thus, the Examiner relies on the tertiary reference of Bernardin et al. Bernardin et al. is relied upon for the teaching of absorbent webs formed from cellulose fibers, used in dressings, whereby the absorbent webs demonstrate improved vertical wicking properties. The improved vertical wicking properties allow for transport of fluid from one location on the web to another remote location, thus providing for increased absorbent capacity of the absorbent web.

Applicant argued, "Bernardin does not teach vertical wicking in the same sense as it is used in Applicant's claims to mean wicking in a direction perpendicular to the plane of the dressing."

This argument was not persuasive. While Bernardin does not teach vertical wicking in the manner that it refers to wicking in a direction 'perpendicular to the plane of the dressing', the Examiner notes that this limitation does not establish any patentable distinction that would accrue over the explicit reference teachings, which provides for the same components as claimed by Applicant. Namely, Bernardin is sufficient for their teaching of absorbent webs formed from cellulose fibers, used in dressings, whereby the absorbent webs demonstrate improved vertical wicking properties, as noted above. No unexpected results have been observed which would occur as a result of the particular direction of wicking (perpendicular wicking of the instant

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invention versus lateral wicking of the art). The art is well aware of providing for absorbent products that demonstrate enhanced wicking capabilities. Furthermore, as noted above, with regards to the limitation of wicking in a direction 'perpendicular to the plane of the dressing', this limitation has not been supported in the specification (see rejection of 35 U.S.C. 112, 1st paragraph above).

Applicant argued, "Applicants' dressing and method are highly unusual in that, when used in the treatment of acute wounds, the dressing adheres to the wound and forms a crust. This type of behavior would usually only be seen with a biological dressing such as allograft, and it is a truly surprising discovery. That the dressing adheres to the wound and acts like a biological dressing when it is not is an unexpected result. Applicants believe that this is due to the modulation of the inflammatory response caused by the vertical wicking property of the dressing. The unexpected results of vertical wicking are also shown in the Examples."

These arguments were not found convincing. The prior art in combination recognizes and teaches wound dressings/absorbent web articles for the treatment of wounds whereby the dressings/webs possess improved vertical wicking properties - the same result sought by Applicant. Thus, it cannot be seen as to how the prior art would be so distinguished from the instant invention as to render the claims non-obvious. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the

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prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Lastly, Applicant argued, "Neither, Carlisle, Dyer, nor Bernardin mention that vertical wicking could be an advantage in a dressing used to treat acute wounds".

This was not persuasive. "The fact that appellant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In this instance, the prior art is well aware of the benefits and advantages that accrue as a result of vertical wicking.

For these reasons, the rejections of record have been maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

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June 30, 2009

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